European Medicines Agency
Inspections

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WORK PLAN FOR GCP INSPECTORS WORKING GROUP FOR 2009

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1. INTRODUCTION

The GCP Inspectors Working Group (GCP IWG) was established by the EMEA in 1997, within the scope of article 57(1)(i) of Regulation (EC) No. 726/2004.

This group focuses on harmonisation and co-ordination of GCP related activities at Community level. The group activities for this year are outlined in this document and the priorities of the group will be:

- Develop processes and capacity building in relation to GCP and inspections of clinical trials conducted in third countries
- Provide guidance in relation to GCP and computer systems
- Provide guidance in relation to quality risk management in clinical trials

2. MEETINGS SCHEDULED FOR 2009

- 03 – 05 March 2009
- 17 – 18 June 2009
- 14 – 15 September 2009
- 09 – 10 December 2009

The following joint meetings will take place:

- Joint meeting with CHMP[1] assessors.
- Joint meeting with the CTFG[2].
- Joint meeting with interested parties.

A number of subgroup meetings to discuss specific topics and draft documents will be organised to coincide with the main meetings when possible but if needed a limited number of additional meetings or teleconferences will be organised (see section 7):

- GCP-GMP[3] subgroup.
- GCP-CMD(h)[4] subgroup.

[1] Committee for Medicinal Products for Human Use
[2] Clinical Trials Facilitation Group
[3] Good Manufacturing Practice
[4] The Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

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- GCP-Advanced Therapy subgroup.
- Guidance on the use of computerised systems in clinical trials subgroup.
- Quality risk management in clinical trials subgroup.

Delegates from this group are also involved in EMEA's multidisciplinary Working Group on 3rd country clinical trials.

3. INSPECTIONS CONDUCTED IN SUPPORT OF THE CENTRALISED PROCEDURE

Development and co-ordination of GCP inspections relating to Centrally Authorised Products.

- This is an ongoing activity and includes coordination of re-inspections when needed.

Maintenance of the information on GCP inspections for Centrally Authorised Products.

- To enter the information on GCP inspections in the EudraCT database.
- To develop a new database for coordination of GCP inspections for Centrally Authorised Products.

4. HARMONISATION TOPICS

Procedures and Guidance documents

- To update, as needed, the existing GCP Inspection procedures and guidance for GCP inspections conducted in the context of the Centralised Procedure.
- To finalise the following guidance on GCP Inspection in accordance with article 29 of Directive 2005/28/EC, and Chapter V, Volume 10 of the Rules Governing Medicinal Products in the European Union, in preparation for publication in that Chapter:
    - Selection of the trials/sites to be inspected:
        - context of assessment of applications for marketing authorisation,
        - surveillance of clinical trials in Member States.
    - Coordination / co-operation with other organisations involved in assessing Good Clinical Practice requirements.
    - Record keeping and archiving of documents obtained or resulting from the Good Clinical Practice inspection.
    - Actions taken after completion of Good Clinical Practice inspection.

Inspection cooperation in the community

a) Cooperation between MS

- To continue with joint inspections of sites involving inspectorates from more than one Member State.

b) Cooperation with 3rd countries

- To develop principles, processes and opportunities for joint inspections with 3rd countries.

Training and development

- Develop peer review of case studies.
- Sharing and discussion of inspection reports, including grading of anonymised findings.
- Develop and monitor opportunities for joint inspections.

- Provision of on the job training and a process for ensuring that all members gain experience through this.
- Development of training tools for GCP inspections.
- Develop opportunities for lectures/workshops at the time of GCP IWG meetings, on special topics, by members of the group and by invited guests.
- Conduct the 7th GCP IWG Training Course to be co-hosted by a National Competent Authority and EMEA in the 3rd or 4th quarter of 2009.
- To develop opportunities for inspectors from developing country authorities to participate in GCP IWG training workshops, to join inspections as observers (e.g. in the context of "Article 58" related GCP inspections) or other related opportunities. To liaise with WHO in this context.

5. TOPICS OF INTEREST

- To continue support for the routine GCP inspection programme supporting the centralised procedure.
- To further develop processes related to GCP and inspections of clinical trials conducted in third countries (ethical and quality considerations) and to support the conduct of inspections in those countries.
- To finalize:
    - Q&A on the documentation and traceability of the IMPs used in bioequivalence studies.
- To finalize the following reflection paper:
    - Reflection paper on expectations for electronic source documents used in clinical trials.
- To develop a reflection paper on quality risk management in clinical trials.
- To further develop inspection processes in the context of:
    - large-scale clinical trials,
    - statistical analysis and reporting,
    - identification of fraud and malpractice.
- To prepare a reflection paper on the conduct of clinical laboratory analyses for clinical trials.
- To support the preparation by the Efficacy Working Party of a guideline on validation of bio-analytical method.
- To discuss and prepare a document with specific triggers for assessors in the context of the assessment of ethical conduct of clinical trials in 3rd countries.
- To develop a processes for communication of GCP non compliance issues.

6. COLLABORATION WITH EUROPEAN COMMISSION

Expert support on GCP related matters, in particular inspection

Implementation of Directive 2001/20/EC and of Directive 2005/28/EC and related guidance documents

- Develop guidance, additional documents related to this, or provide input and advice on guidance or other texts being prepared by the Commission - as requested by the Commission and in conjunction with other parties as appropriate.
- To advise on the necessary modifications to Directive 2005/28/EC and related GCP guidelines in the context of the Advanced Therapy regulation.
- To advise on the necessary modifications to GCP guidelines in the context of the Paediatric regulation.

EudraCT Database

- To advise the EudraCT TIG, when needed, on inspection issues related to further development of the database and in particular in the development of the pediatric module as required by the pediatric regulation.

EU enlargement

- To assist Croatia, Former Yugoslav Republic of Macedonia and Turkey to develop their GCP Inspection roles. To further develop contacts and collaboration with Croatia, Former Yugoslav Republic of Macedonia and Turkey in the field of GCP Inspections.
- These countries are invited to observe meetings of the GCP Inspectors Working Group.

Regulation on Advanced Therapies

- To monitor the implementation of GCP guidelines on ATIMPs in clinical trials of advanced therapies.

Paediatric Regulation

- To establish good working contacts and input with the Paediatric network once it is set up.

Variations Regulation

- To contribute as necessary to the development of proposals for improving the regulation of post-authorisation changes in particular where an impact on GCP inspection resources is foreseen.

7. LIAISON WITH OTHER GROUPS

GMP/GDP[5] IWG

- To maintain a dialogue with the GMP Inspectors Working Group, in particular through the GCP/GMP subgroup, on areas of common interest at the interface between GMP for investigational medicinal products and GCP.

Ad Hoc PhV IWG[6]

- To maintain a dialogue with the Ad Hoc Pharmacovigilance Inspectors Working Group on areas of common interest and in particular concerning pharmacovigilance in relation to clinical trials.

[5] Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group

[6] Pharmacovigilance Inspectors Working Group

CTFG[7]

- Collaboration on areas of mutual interest and in particular in the area of supervision of clinical trials conducted in the Community.

CMD(h)

- To maintain a dialogue with CMD(h), in particular through the GCP/CMD subgroup, on areas of common interest and in particular concerning Bioequivalence/Bioavailability studies.

Heads of Medicines Agencies

- When requested to collaborate on HMA initiatives in GCP-related areas, in particular in the area of supervision of clinical trials conducted in the Community and in relation to inspections in 3rd countries.
- To contribute to the development of the benchmarking scheme (BEMA) regarding interactions with GCP processes.

PIC/S[8]

- Ongoing collaboration on areas of mutual interest to ensure harmonisation or equivalence in inspection processes and related matters, and an efficient use of Community inspection related resources.

Other Regulatory Agencies

- Development of contacts between EU and 3rd country agencies, on GCP matters.
- To develop inspection processes and contacts in the context of clinical trials conducted in developing countries through liaison with WHO and developing country inspectorates. To co-operate with wider international partners on the sharing of inspection information.
- Develop contacts with the paediatric network.

Other Bodies

- Develop contact with Ethics Committees, including the preparation of a possible joint meeting.

[7] Clinical Trials Facilitation Group
[8] Pharmaceutical Inspection Co-operation Scheme